REMARKS

Status of the Claims

Claims 1-7 are currently amended and claims 12-14 and 22 are currently canceled.

Claims 1-7 have been amended to recite that the phospholipase D catalyzed reaction is conducted under nitrogen. Support for this amendment is found on Page 7 of the Specification.

Claims 1-7 have been amended to recite that the phosphatide product is 95% pure. Support for this amendment is found in the table bridging pages 4-5 of the Specification and in Examples 2, 3, 4 and 5 on pages 7-13 of the Specification.

Claims 12-14 have been canceled.

Claim 20 has been amended to depend from claims 1-7.

Claim 22 has been added, and it specifies that the phosphatide reactants of claims 1-7 are completely converted to product. Support for this amendment is found in the table bridging pages 7-9 of the Specification and in the Examples.

The claims have been amended to more clearly describe the present invention.

No new matter has been added.

1. The Non-Finality of the Office Action

Applicants submit that the Examiner has improperly made this Office Action final because the Examiner has imposed rejections over prior art references not previously cited. Accordingly, Applicants respectfully request that the Examiner remove the finality of this Office Action.

Applicants have submitted an Information Disclosure Statement (IDS) concurrent with this Response. Since Applicants believe the outstanding Office Action was improperly made final, Applicants submit that the concurrently filed IDS should be considered as being filed before a final rejection.

2. The Status Identifiers of Claims 20 and 21

The Examiner has required correction of the status identifiers of claims 20 and 21. Applicants have made the required corrections.

3. Claim Rejections under 35 USC §112, First Paragraph

The Examiner has rejected claims 20 and 21 as allegedly failing to meet the written description requirement. The Examiner contends that there is no support in the Specification for the claim limitation that the phosphatidyl-L-serine (PS) sodium salt composition is at least 95% pure and completely converted PS sodium salt (Office Action, pages 2-3). Applicants respectfully traverse.

Applicants have canceled claim 22, thereby obviating the "completely converted" prong of the rejection.

Support for the 95% purity limitation is found in the table bridging pages 4-5 in the Specification and Examples 2, 3, 4 and 5 on pages 7-13 of the Specification. Applicants submit that the cited disclosure provides sufficient written support.

4. Claim Rejections under 35 USC §112, Second Paragraph

The Examiner has rejected claims 5-8 as allegedly vague and/or indefinite. The Examiner contends that claims 5 and 6 appear internally inconsistent as being directed to a sodium salt, yet the R1 moiety is hydroxyl (Office Action, page 3). Applicants respectfully traverse.

Applicants submit that the claims are, in fact, consistent because they are drawn to pharmaceutical PS compositions in which the PS forms a sodium salt. A person of skill in the art would recognize that the claimed pharmaceutical composition comprises a positively charged sodium atom which forms a salt with the negatively charged PS.

5. Claim Rejections under 35 USC §102

The Examiner has imposed anticipation rejections based on four different prior art references:

(a) Sakai (US Patent #6,117,853);

(b) De Tommaso (US Patent #6,326,406);

(c) Koch (The Journal of Biological Chemistry, 1907); and

(d) Brajtburg (Antimicrobial Agents in Chemotherapy, 1990).

Applicants respectfully traverse.

5(a) Sakai

The Examiner has rejected claims 1-9, 11, 15 and 17-21 as allegedly anticipated by Sakai. The Examiner contends that Sakai discloses a PS sodium salt composition that has the same structure as

the claimed composition and is recognized to be useful as a food additive or pharmaceutical for oral administration (Office Action page 4). Applicants respectfully traverse.

By way of preliminary matters, Applicants have amended the claims to recite that the PS is at least 95% pure. Applicants also point out that the claims have always recited that the presently claimed PS is made in an enzymatic reaction catalyzed by phosolipase D (PLD) obtained from *Streptomyces hachijoense*. In contrast, Sakai teaches a method of making PS in an enzymatic reaction catalyzed by PLD obtained from *Streptomyces prunicolor*.

With these points in mind, Applicants direct the Examiner's attention to the enclosed Declaration of Giampaolo Menon, who is a person of skill in the phosphatide art and a co-inventor of the present application. In his declaration, Mr. Menon provides experimental results which demonstrate that the first step of the two-step PS purification process taught by Sakai (Column 4) in fact produces a composition comprised of approximately 40% phosphatidyl choline, 40% PS and 15% phosphatidic acid together with two faint spots of unknown identity. (See Figure 1 of the Menon Declaration).

Mr. Menon provides further experimental results which demonstrate that the second step of Sakai's PS purification method, a silica column purification step, in fact yields no PS product at all when performed as described in Column 4. Moreover, Mr. Menon modified the silica column in an effort to recover PS product; but a 4:1 methanol:chloroform elution buffer failed to elute anything from the column, and a water saturated methanol-chloroform elution buffer eluted a fraction from the silica column having PS:PA in a ratio similar to that of the product obtained from the first part of the Sakai PS production process. (See figure 2 of the Menon Declaration).

In view of foregoing claim amendments and experimental results, Applicants submit that the Sakai reference teaches a PS product of only 40% purity which falls outside the presently claimed 95% purity level. In the alternative, the Sakai reference teaches no PS product at all, which also falls outside the presently claimed PS products. Moreover, Applicants point out that Sakai fails to teach PS in a sodium salt, as presently claimed. It follows that Sakai et al. is not an anticipating reference, and Applicants respectfully request reconsideration and withdrawal of this rejection.

5(b) De Tommaso

The Examiner has rejected claims 1, 3 and 5-6 as allegedly anticipated by De Tommaso because the Examiner contends that De Tommaso teaches a PS sodium salt that has a fatty acid composition identical to the presently claimed PS and a peroxidation value less than 5 (Office Action page 5). Applicants respectfully traverse.

Applicants point out that the De Tommaso patent discloses a reaction involving glycocholate and soybean lecithin, which is followed by the addition of propofol to yield a pharmaceutically acceptable salt of a bile acid and a lecithin in a propofol composition (column 4, lines 41-49 and the abstract). The composition taught by De Tommaso et al. is therefore structurally distinct from that presently claimed PS. On these grounds, Applicants submit that the anticipation rejection is improper, and respectfully request its reconsideration and withdrawal.

5(c) Koch

The Examiner has rejected claims 1 and 4-6 as allegedly anticipated by Koch because the Examiner contends that Koch discloses a PS sodium salt that has a fatty acid composition identical to egg lecithin and which is presumed to have a degree of peroxidation less than 5 (Office Action page 6). Applicants respectfully traverse.

Applicants point out that Koch discloses lecithin and kephalin molecules, which have chemical structures that are distinct from the presently claimed PS (Koch page 56). Accordingly, Applicants submit that the rejection is improper, and respectfully request its reconsideration and withdrawal.

5(d) Brajtburg

The Examiner has rejected claims 1 and 4-6 as allegedly anticipated by Brajtburg because the Examiner contends that this reference discloses a PS sodium salt that has a peroxidation value of less than 5 (Office Action, page 7). Applicants respectfully traverse.

Applicants submit that Brajtburg does not disclose PS, but rather discloses salt compositions comprised of egg lecithin and glycolic acid (Brajtburg et al. column 1, 2nd paragraph). Because Brajtburg fails to disclose the presently claimed PS compositions, it is not an anticipating reference. Applicants therefore respectfully request reconsideration and withdrawal of the rejection.

6. Claim Rejections under 35 USC §103

The Examiner has also imposed, in the alternative to the above-discussed anticipation rejections, obviousness rejections over the combination of the De Tommaso, Koch and Brajtburg references. In addition, the Examiner has rejected claims 1-11 and 15-19 over Sakai taken in combination with Horribin, Puricelli, Chemical Land 21 and Kurihara (Office Action pages 3 – 10).

Applicants submit that, as discussed above in the anticipation section, none of the prior art references of record anticipate the presently claimed PS sodium salt pharmaceutical compositions having a 95% degree of purity and a peroxidation value less than five. Since all of the prior art references have the same deficiency, the prior art references of record, even when combined, fail to teach or suggest the presently claimed PS sodium salt compositions. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness, and the rejection is improper. Applicants therefore request reconsideration and withdrawal of the obviousness rejections.

7. Conclusion

In view of the above-discussed claim amendments, experimental evidence and remarks, Applicants respectfully request allowance of the claims, which are drawn to subject matter that meets all statutory requirements for patentability.

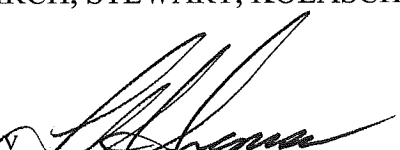
Pursuant to the provisions of 37 C.F.R. 1.17 and 1.136(a), Applicants have petitioned for a three (3) month extension of the period to file a Reply to the Office Action issued January 8, 2007, to July 8, 2007. The required fee has been paid in connection with the filing of this response.

Should there be any outstanding matters that need to be resolved in the present application; the Examiner is respectfully requested to contact Leonard R. Svensson (Reg. No. 30,330) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP



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